K100548

510(k) Summary of Safety and Effectiveness

SUBMITTER:	Covidien LP (formerly registered as Tyco Healthcare, LP) 60 Middletown Avenue North Haven, CT 06473 USA
CONTACT PERSON:	Angela Van Arsdale Associate II, Regulatory Affairs
DATE PREPARED:	February 19, 2010
TRADE/PROPRIETARY NAME:	Versaport™ Bladeless Low Profile Trocar
COMMON/USUAL NAME:	Surgical Trocar
CLASSIFICATION NAME:	Endoscope and Accessories
PREDICATE DEVICE(S):	Versaport™ Bladeless Trocar
DEVICE DESCRIPTION:	The Versaport™ Bladeless low profile housing design is available in 2mm-3mm to 5mm in various lengths with radiolucent fixation sleeve. The 2mm-3mm to 5mm Versaport™ seal system accommodates 2mm-3mm to 5mm instrumentation respectively. There is a luer lock with cap for insufflation and rapid desufflation (in place of a stopcock).
INTENDED USE:	The Versaport™ Bladeless Low Profile trocar is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.
TECHNICAL CHARACTERISTICS:	The Versaport™ Bladeless trocar with Low Profile design and and radiolucent fixation sleeve is equivalent to the predicate devices in terms of its intended use. The 5mm size(s) change only includes the low profile housing and seal design. The Versaport™ seal system in the low profile housing has been modified to fit the low profile design, containing an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or withdrawn accommodating 2mm-3mm to 5mm instrumentation respectively. There is a luer lock with cap (in place of a stopcock) for insufflation and rapid desufflation. The Versaport™ Bladeless 2mm-3mm to 5mm sized low profile trocars come in the same various lengths and radiolucent fixation sleeves as the predicate. The 2mm-3mm size has an obturator tip with 2 linear non-bladed fins and a non-bladed rounded tip.
MATERIALS:	All components of the Versaport™ Bladeless Low Profile trocar are comprised of materials which are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	In-vitro and in-vivo tests were performed to verify that the performance of the Versaport™ Bladeless Low Profile trocar is substantially equivalent to the predicate device(s), and to validate that the Versaport™ Bladeless Low Profile trocar will perform as intended.

APR 2 3 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 2 3 2010

Covidien LP
% Ms. Angela Van Arsdale
Associate II, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K100548
Trade/Device Name: Versaport™ Bladeless Low Profile Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 05, 2010
Received: April 06, 2010

Dear Ms. Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buehler for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K100548

Device Name:

VERSAPORT™ Bladeless Trocar

Indications For Use:

The Versaport™ Bladeless Trocar is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for mxn

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100548

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